DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

May 3, 1999

WARNING LETTER
SJN-99-08

CERTIFIED MAIL
Return Receipt Requested

Luis Fullana
President
Industria Lechera de Puerto Rico
P.O. Box 362949
San Juan, Puerto Rico 00936-2949

Dear Mr. Fullana:

The Food and Drug Administration (FDA) conducted an inspection on March 2, 5, 8, 10, 12 & 17, 1999 of your milk and milk product manufacturing facility located at 198 Chardon Ave. Hato Rey, P.R. 00919. At the conclusion of the inspection, our Investigator presented and discussed with you an FDA-483, Inspectional Observations form, listing several deviations from Title 21, Code of Federal Regulations, Part 113, Thermally Processed Low Acid Foods Packaged in Hermetically Sealed Containers and Part 110 Good Manufacturing Practice Regulations. These deviations are in connection to your firm's aseptic processing of Ultra High Temperature (UHT) fluid (whole, skim and lowfat 2%) milk products causing these to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to consistently record process and production information at appropriate intervals and at the time they are observed by the operator in accordance with 21 CFR 113.40(g)(1)(ii)(e), 113.40(g)(2)(ii)(c), 113.100(a), & 113.100(a)(4). We refer you to FDA-483, observations 1 to 4. For example:

a) product temperature in the [redacted] sterilizer holding tube outlet was not recorded for the milk production of 3/1/99, 3/2/99, 2/19/99, and 1/29/99;

b) hydrogen peroxide concentrations are not determined and hydrogen peroxide levels are not consistently read during aseptic packaging, for instance, during production of 1/29/99 Tetra-Pak 4, Shift 1 and 7/28/98, Tetra-Pak 3, Shift 1 these processing factors were not documented;

c) hermetic seal closure evaluations for the UHT container are not being routinely done and documented as required in 21 CFR 113.60(a)(3) and 113.100(c), for instance, during production of 5/8/99 and 8/3/98 on Tetra-Pak 2, Shift 2, such checks were not recorded as done; and

d) product flow rate is not recorded for both the [redacted] and the Tetra Therm Flex I product-to-product regenerator systems, no instrument to read product flow rate is installed in these systems although this is specified as a critical factor in the filed scheduled process. Note that the record of product flow rate could be the record associated with the operation of the timing pump or as determined by filling and closing rates. In the first instance, for example, the homogenizer might be serving as the timing or metering pump and typically there is a recording of the homogenizer operation which can be translated or correlated to a product flow rate. Likewise, fill and seal rates can be used to calculate product flow rate provided no aseptic surge tank is in use.

2. Failure to review and sign processing and production records no later than one (1) working day after the actual process and before release for distribution by a qualified representative of the plant management as required in 21 CFR 113.100(b).

3. Failure to assure proper operation of production and processing equipment through an adequate calibration program in accordance with 21 CFR 113.40. We refer you to FDA-483 Observations 6 to 8. For example:

a) the differential pressure recorder-controller of the [redacted] regenerater is not checked for accuracy against a known standard at least once every 3 months as required by 21 CFR 113.40(g)(1)(i)(e), and no calibration identifying tag or seal is used;

b) there is no assurance that the temperature indicating device and temperature recording device for the [redacted] sterilizer are checked for accuracy in accordance with 21 CFR 113.40(g)(1)(i)(a) and 113.40(g)(1)(i)(b) in that, no calibration identifying tag or seal is displayed nor are calibration records kept.

4. Failure to provide for coding completeness on the UHT milk product containers in that, the code system used does not identify the establishment where packed and the date and year packed as required in 21 CFR 113.60(c).

Furthermore, the use of hydrogen peroxide solution to sterilize the UHT milk containers must be monitored, by analytical testing of samples, to assure it meets the 0.5 ppm residue limit in accordance with 21 CFR 178.1005(d). This observation was verbally brought to the attention of Mr. Pedro Trinidad during the inspection. Mr. Trinidad indicated that this was being done years ago but was discontiued. We advise you that such testing is required to be done during each production run packaging operation.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As the most responsible official at the firm, it is your responsibility to assure that this facility is operated in compliance with the applicable FDA laws and regulations. A copy of the pertinent sections of 21 CFR cited are attached for your reference.

Although these observations warrant consideration for formal regulatory follow-up, we are affording you an opportunity to voluntarily correct the noted deviations. Failure to promptly correct these may result in regulatory action without further notice. These actions include seizure and/or injunction.

Please notify the San Juan District office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations. An adequate response would include a review of pertinent processing records by your process authority.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Andres Toro, Compliance Officer.

Sincerely,

Matthew Eckel
Acting District Director

cc:

Pedro Trinidad
Investigations and Development Manager
Industria Lechera de Puerto Rico
P.O. Box 362949
San Juan, Puerto Rico 00936-2949